



NATIONAL TOXICOLOGY PROGRAM

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November 1, 2007

To: NTP Board of Scientific Counselors

From: Director, Office of Nominations, National Toxicology Program

Subject: New Toxicology Study Nominations and Research Concepts for Review

The enclosed material is provided as background for review of NTP study nominations and draft research concepts at the December 6, 2007 NTP Board of Scientific Counselors (BSC) meeting. The BSC is asked to review the material as explained below.

The NTP has a formal multi-step process for reviewing new study nominations before selections for testing are made and studies are initiated. The first external step in this process is a review by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC). The ICCEC reviewed ten new study nominations in December 2006. The preliminary study recommendations for these nominations and a request for public comment were published in the *Federal Register* March 29, and through the NTP's newsletter and website. Four of these new study nominations were reviewed by the BSC at the June 22, 2007 meeting. For the December 6, 2007 meeting, the remaining six of these new nominations (aminopyridines, diethyl phthalate, 2',2''-dithiobisbenzanilide, 2-methoxy-4-nitroaniline, nanoscale gold, and pentaethylenhexamine) will be reviewed. This public meeting also provides an additional opportunity for program staff and the BSC to receive public comment on these nominations. The six nominations under consideration and the corresponding preliminary study recommendations are summarized in the attached table.

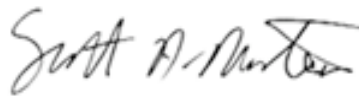
Based on the preliminary study recommendations and any public comments received, NTP staff scientists developed Draft Research Concepts for each nomination recommended for study. Research concepts are brief documents describing the NTP's initial thoughts on a proposed research program to address a given nomination and serve to facilitate an additional level of external review of nominations to the NTP testing program. Draft research concepts for five of the new nominations are enclosed. Pentaethylenhexamine is not recommended for study, and thus a research concept has not been developed. A brief summary of this nomination is enclosed.

In addition, a draft research concept for a series of studies on di(2-ethylhexyl)phthalate and phthalate mixtures ("Phthalates Initiative") will be reviewed. This research program does not stem from a new nomination, but relates to several ongoing NTP study programs and prior nominations, as well as critical data needs identified by the NTP Center for the Evaluation of Risks to Human Reproduction.

The NTP asks the BSC to provide its general views on the merit of these study nominations, advise whether the proposed study approach or any additional studies are an appropriate use of the NTP's resources, and offer its perspective on any public comments received on these nominations. To facilitate the BSC review, specific charge questions for each draft research concept are enclosed.

The March 29 *Federal Register* notice, public comments received, and background documents supporting each of these nominations are provided on the enclosed CD, and are also available electronically on the NTP web site at <http://ntp.niehs.nih.gov/go/29287>.

Please contact me by telephone at (919) 541-5710 or by email at masten@niehs.nih.gov if prior to the December 6 meeting you have questions or comments regarding any of the nominations or background material. If there are other background materials, such as references cited in any of the enclosed documents, that would facilitate your review, I would be happy to provide them.

A handwritten signature in black ink, appearing to read "Scott A. Masten". The signature is fluid and cursive, with the first name "Scott" and last name "Masten" clearly distinguishable.

Scott A. Masten, Ph.D., DABT

Enclosures